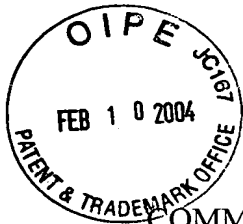


Image

1641



Docket No.: 210190US0PCT

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 09/857,213
Applicants: Osamu MIYAZAKI
Filing Date: June 22, 2001
For: MONOCLONAL ANTIBODY AGAINST
APOLIPOPROTEIN A-I
Group Art Unit: 1641
Examiner: B. Nguyen

SIR:

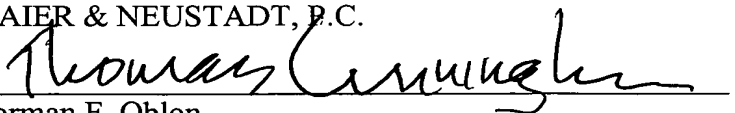
Attached hereto for filing are the following papers:

Declaration Under 37 C.F.R. 1.132 (executed)

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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DOCKET NO: 210190US0PCT



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

OSAMU MIYAZAKI

: EXAMINER: NGUYEN, B.

SERIAL NO: 09/857,213

:

FILED: JUNE 22, 2001

: GROUP ART UNIT: 1641

FOR: MONOCLONAL ANTIBODY
AGAINST APOLIPOPROTEIN A-I

:

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Osamu Miyazaki who deposes and states:

Nihon University Graduate School of

1. That I am a graduate of Agriculture Research and received a

Master's degree in the year 1992.

Daiichi Pure Chemicals Co., Ltd.

2. That I have been employed by _____, for 12 years as a researcher in

the field of Biochemistry.

3. That I understand the English language or, at least, that the contents of the

Declaration were made clear to me prior to executing the same.

4. That the following experiments were carried out by me or under my direct supervision and control.

Experiment

Monoclonal antibodies 55205 and 55207 were prepared in the same manner as described in Example 1 of the present application.

Supplemental Example 1:

Supplemental Example 1 was carried out by the Western blotting method as described in Example 2(1) of the present application. As shown in Supplemental Fig. 1, monoclonal antibody 55205 (lane 5) and monoclonal antibody 55207 (lane 7) exhibit a unique bands corresponding to apoA-I of a molecular weight of 28,000 Da. While monoclonal antibody 14208 (lane 9) also binds to apoA-I of a molecular weight of 28,000 Da, as shown below, it has a different specificity than monoclonal antibodies 55201, 55205 and 55207, which bind to HDL containing apo-A1 alone.

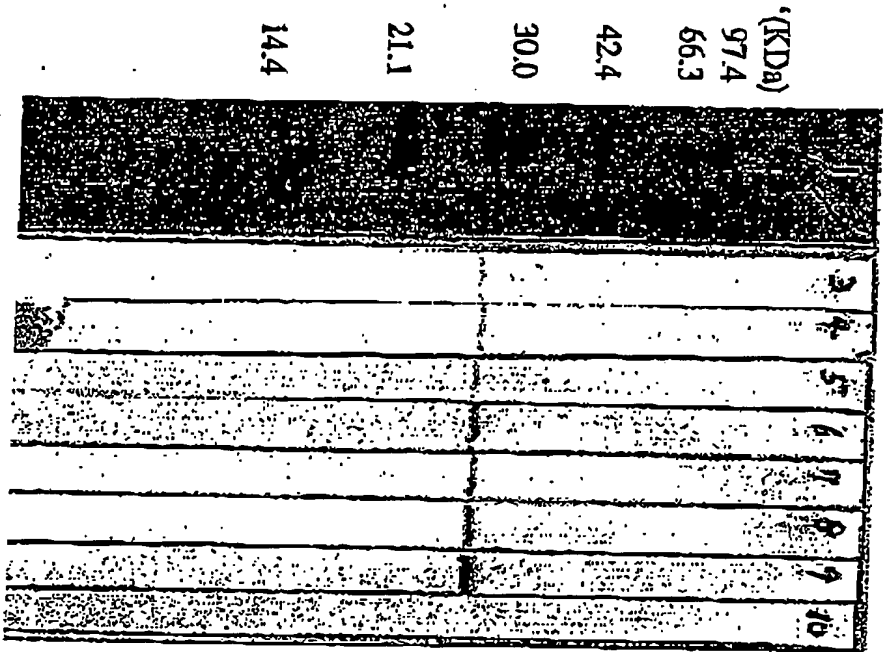
Supplemental Example 2:

Supplemental Example 2 was carried out by the Elisa method as described in Example 2(2) of the present application. As shown in Table A, monoclonal antibody 55205 and monoclonal antibody 55207 did not react with HDL containing apoA-II (GtXapoA-II), but reacted specifically with HDL containing apoA-I alone (GtXapoA). By contrast, monoclonal antibody 14208 was reactive with both HDL containing apoA-I and HDL containing apoA-II.

Supplemental Example 3:

Supplemental Example 3 was carried out by the same manner as described in Example 2(3) of the present application. As shown in Supplemental Fig. 3 (lower), monoclonal antibody 55205 and monoclonal antibody 55207 exhibited a similar pattern to antibody 55201, regarding the reactive with respect to fractions separated through gel filtration.

Supplemental Fig. 1



No.	Antibodies
5	55205
7	55207
9	14208
10	Normal Mouse IgG



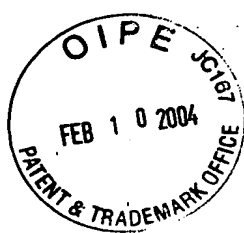
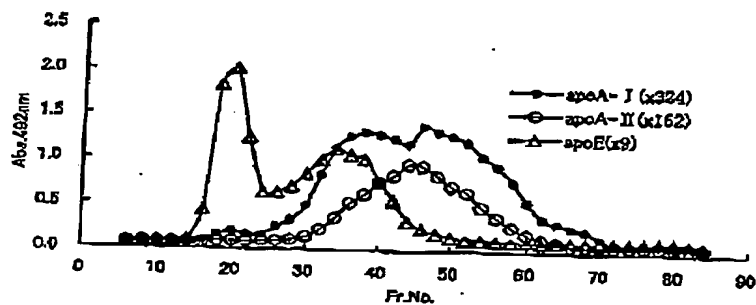


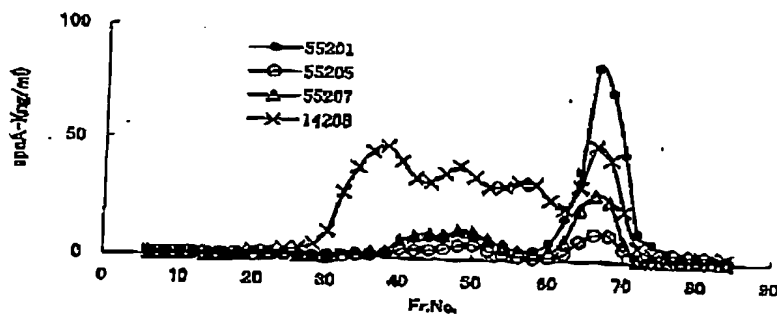
Table A

	Abs.492nm	
	GtXapoA-I	GtXapoA-II
55201	1.517	0.089
55205	1.716	0.083
55207	1.343	0.106
14208	1.302	1.308

Supplemental Fig. 2



Supplemental Fig. 3



5. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

6. Further deponent saith not.

Osamu Miyazaki
Signature

January 30, 2004
Date

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